DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5149. Testosterone, desoxycorticosterone acetate, and progesterone. (F. D. C. No. 38566. S. Nos. 3–583 M, 8–859 M, 8–871 M.)

INFORMATION FILED: 5–21–56, S. Dist. Calif., against Coast Chemical Co., a corporation, and Cleo O. Bedwell, president.

SHIPPED: Between 11–9–54 and 2–1–55, from California to Arizona and Massachusetts.

LABEL IN PART: (Btl.) "10 cc Sterile Multiple Dose Vial Testosterone Crystalline U. S. P. In Aqueous Macrosuspension 50 Mgs. per cc Preservative: Merthiolate—1:20 M For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription. Made especially for Star Pharmacy, Wholesale Division Boston & Cambridge 39, Mass.," "10 cc Sterile Desoxycorticosterone Acetate U. S. P. Aqueous Macrosuspension of Desoxycorticosterone Acetate 5 mgs. per cc When Properly Shaken Purified Crystalline Adrenal Cortical Hormone preparation. Coast Pharmaceuticals Division of Coast Chemical Co. Los Angeles California," "Lot No. 5997 Caution: Federal law prohibits dispensing without prescription. For Intramuscular Injection Only," and "10 cc Sterile Progesterone U. S. P. In Aqueous Macrosuspension When properly shaken, each cc contains: Progesterone 50 mgs. (50 I. U.) Preservative: Merthiolate—1:20 M For Intramuscular Use Only Distributed by Rocky Mountain Pharmacal Co. Phoenix, Arizona * * * Caution: Federal law prohibits dispensing without prescription."

CHARGE: 501 (c)—when shipped, the purity and quality of the *testosterone* and *desoxycorticosterone acetate* fell below that which they were represented to possess in that these articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms; and 502 (a)—the word "Sterile" in the labeling of the *progesterone* was false and misleading since the article was not sterile but was contaminated with viable micro-organisms.

PLEA: Nolo contendere.

DISPOSITION: 8–1–56. Corporation fined $450 and individual $225. Corporation also placed on probation for 1 year.

5150. Dexatal tablets (Gracital). (F. D. C. No. 39243. S. No. 22–883 M.)

QUANTITY: 400 100-tablet btls. at Meriden, Conn.

SHIPPED: 10–6–55, from Worcester, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "Product No. 10 Graco Gracital Dextro Amphetamine Sulfate and Amobarbital C. T. Caution: Federal law prohibits dispensing without prescription * * * Each tablet contains: Dextro Amphetamine Sulfate, 5 mg. * * * Note: New Product Name Gracital Formerly Called Dexatal."

RESULTS OF INVESTIGATION: Examination showed that the article contained no significant amount of dextro-amphetamine sulfate.

LIBELED: 5–23–56, Dist. Conn.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 5 mg. of dextro-amphetamine sulfate; and

*See also No. 5141.

502 (a)—the labeling of the article contained the false and misleading statement "Each tablet contains: Dextro Amphetamine Sulfate 5 Mg."

DISPOSITION: 8–27–56. Consent—destruction.

5151. Elixir Cena-B. (F. D. C. No. 38957. S. No. 47–455 M.)

QUANTITY: 52 1-pt. btls. and 4 1-gal. btls. at Irvington, N. J.

SHIPPED: 1–21–56, from Long Island City, N. Y., by Ormont Drug & Chemical Co., Inc.

LABEL IN PART: (Btl.) "Elixir Cena-B Alcohol 21% By Volume."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially more than the declared amount of phenobarbital.

LIBELED: 2–20–56, Dist. N. J.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each 5 cc (1 Teaspoonful) Contains: Phenobarbital (¼ Gr.). . . . 16.0 Mg." was false and misleading.

DISPOSITION: 3–27–56. Default—destruction.

5152. Rauwolfia serpentina (powder and tablets). (F. D. C. No. 37372. S. Nos. 84–971 L, 84–973 L.)

QUANTITY: 1 drum containing 119 lbs., 1 drum containing 110¼ lbs., and 100,000 tablets at Philadelphia, Pa.

SHIPPED: 9–15–54 and 10–22–54, from New York, N. Y., by Prentiss Drug & Chemical Co., Inc., and Fine Chemical Co.

RESULTS OF INVESTIGATION: The article (powder) was shipped to Philadelphia, Pa., and after its arrival, a portion of the bulk powder was used to prepare the above-mentioned tablets, each of which contained 100 mg. of the powder.

Examination of the article (powder and tablets) showed that it contained the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina*.

LIBELED: 11–24–54, E. Dist. Pa.

CHARGE: 501 (d) (2)—the article (powder and tablets) was represented as *Rauwolfia serpentina* when shipped, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor; and 502 (a)—the designation "Rauwolfia Serpentina" on the drum labels of the article was false and misleading since such designation represented and suggested that the article consisted wholly of *Rauwolfia serpentina*, whereas such was not the case.

DISPOSITION: Gane & Ingram, Inc., New York, N. Y., appeared as claimant and filed an answer denying that the article was adulterated or misbranded. The case came on for trial before the court without a jury; and, at its conclusion, the court, on 1–28–56, entered a decree condemning the article and ordering its destruction.

5153. Citru-Mix. (F. D. C. No. 39047. S. No. 35–465 M.)

QUANTITY: 48 2-oz. jars at Richmond, Ind.

SHIPPED: During September 1950, from Grand Rapids, Mich.

LIBELED: 5–18–56, S. Dist. Ind.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 5 mg. of vita-